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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,621	02/08/2002	Peter B. Reiner	100103.402	3213

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EXAMINER
SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
1635	6

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/072,621	Reiner et al.
Examiner	**Art Unit**
Mary Schmidt	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL.** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-15, drawn to methods of regulating expression of amyloid precursor protein in a cell comprising regulating expression of an ABC transporter, classifiable in class 514, subclass 2 or 44.

   II. Claims 16 and 17, drawn to methods of determining whether a human host is afflicted with a condition suitable for treatment with an agent that regulates expression of amyloid precursor protein comprising measuring the expression level of an ABC transporter in a brain cell, classifiable in class 435, subclass 4 or 6.

   III. Claims 18 and 19, drawn to transgenic animals and use of said animals for screening, classifiable in class 800, subclasses 3 and 8.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The methods of Group I are drawn to regulation of the ABC genes or proteins. The methods of Group II are methods of screening for expression levels of

ABC genes or proteins, but do not involve the step of administration of an agent that regulates the expression of the ABC gene or protein levels.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The methods of Group II are drawn to methods of screening for ABC expression levels in humans. The methods of Group III are drawn to use of non-human transgenic animals having recombinant expression of an ABC gene. The methods of Group I do not involve transgenic manipulation of a human.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The methods of Group I are drawn to regulation of an ABC gene or protein in a cell, but do not involve making a transgenic non-human animal as claimed in Group III.

3. Upon election of any of Groups I-III above, the following restriction is required to the type of ABC transporter claimed. The following ABC transporters are disclosed in the specification as filed:

A. ABCB9 (instant SEQ ID NOS. 1 and 6), applicable to claims 1-3, 6-10, 13-19;

B. ABCB1 (instant SEQ ID NOS. 2 and 7), applicable to claims 1-2, 6-9, 13-19;

C. ABCA2 (instant SEQ ID NOS. 3 and 8), applicable to claims 1-2, 6-9, 13-19;

D. ABCG4 (instant SEQ ID NOS. 4 and 9), applicable to claims 1, 2, 4, 6-9, 11, 13-19;

E. ABCG1 (instant SEQ ID NOS. 5 and 10), applicable to claims 1, 2, 5-9, 12-19.

Each ABC transporter detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences as per MPEP 803.04.

MPEP 803.04 states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Examination will be restricted to only the elected ABC transporter sequence.

4. Furthermore, upon election of Group I above, claims 1-15 are further restricted to the type of regulatory molecule claimed as follows:

Ia. Claims 1-6, 8-12 and 14-15, drawn to methods of regulating expression of amyloid precursor protein in a cell comprising regulating expression of an ABC transporter with an antisense molecule, classifiable in class 435, subclass 375, and/or class 514, subclass 44.

Ib. Claims 1-5 and 7-15, drawn to methods of regulating expression of amyloid precursor protein in a cell comprising regulating expression of an ABC transporter with a small molecule compound, classifiable in class 435, subclass 375.

Ic. Claims 1-5, and 7-15, drawn to methods of regulating expression of amyloid precursor protein in a cell comprising regulating expression of an ABC transporter with a peptide molecule, classifiable in class 435, subclass 375, and/or class 514, subclass 2.

5. The inventions are distinct, each from the other because of the following reasons:

6. Inventions Ia-Ic are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The antisense of Group Ia. are short oligonucleotide compositions which operate to regulate the gene expression by hybridization to the target gene and subsequent degradation of the expressed target gene prior to translation. The

small molecule compounds of Group Ib. operate in different ways, often by binding the transporter receptor in an antagonist fashion. The peptides of group Ic. are protein compositions which may operate as an antagonist to the receptor binding domain. The antisense, small molecule and peptide compositions thus have distinct chemical structures corresponding to distinct modes of operation for the claimed effects of regulating expression of the target ABC transporter.

7. Applicant is advised that the reply to all of the above requirements to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to *Katrina Turner*, whose telephone number is (703) 305-3413.

M. M. Schmidt
November 16, 2002